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10/789,964	02/27/2004	James A. Esler	300567	9180

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FAEGRE & BENSON LLP
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EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
11/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/789,964	ESLER ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,18-25 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18-25 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 7/1/09. Claims 1-13, 18-25, and 28-31 remain pending. No claims have been amended.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (US 2003/0153819 A1) in view of Saltzstein et al. (5,941,829) in view of Norris et al. (US 2002/0026103 A1), and further in view of Kelliher et al. (5,857,194).

(A) Referring to claim 1, Iliff discloses a system for automatically populating medical device data into one or more databases, comprising:

a system controller including a processor and a computer readable medium, wherein the computer readable medium includes instructions executable by the processor to (para. 84-85 of Illiff):

receive a data set comprising objective data, the objective data comprising objective data about a first patient (para. 13 of Iliff);

receive a data set comprising subjective data, the subjective data comprising subjective data about the first patient (para. 13 of Iliff);

populate the objective data and the subjective data into a first database having one or more database records associated with the first patient (para. 14 of Iliff);

receive a first data set that is associated with the first patient, the first data set having a first date and time stamp associated with it (para. 223 of Iliff);

receive a second data set that is associated with the first patient, the second data set having a second date and time stamp associated with it (para. 223 of Iliff);

populate the first data set into the one or more database records associated with the first patient (abstract, para. 90, para. 145, and para. 223 of Iliff); and

populate the second data set into the one or more database records associated with the first patient (abstract, para. 90, para. 145, and para. 223 of Iliff).

Iliff does not expressly disclose: the data sets are collected by a physician, automatically validate the objective data and the subjective data, the data sets are from an implantable medical device, and wherein the date and time stamps are configured to act as database record locators.

Saltzstein discloses that the physician collects the data and automatically validating the data (col. 5, line 47-53 and col. 7, lines 6-8 of Saltzstein).

Norris discloses receiving data sets from an implantable medical device (para. 79 of Norris).

Kelliher discloses wherein the stamps are configured to act as database record locators (col. 3, line 62 – col. 4, line 7 of Kelliher).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Saltzstein, Norris, and Kelliher within Iliff. The motivation for doing so would have been
to detect errors (col. 7, lines 6-8 of Saltzstein), help physicians better manage chronically ill patients (para. 21 of Norris), and to find the records by searching (col. 3, line 62 - col. 4, line 7 of Kelliher).

(B) Referring to claim 2, Iliff discloses receiving objective data and subjective data (see para. 13 of Iliff). However, Iliff and Saltzstein do not disclose receiving implantable medical device data associated with additional patients; and populating the implantable medical device data into one or more database records of the first database associated with each of the additional patients.

Norris discloses receiving implantable medical device data associated with additional patients; and populating the implantable medical device data into one or more database records of the first database associated with each of the additional patients (para. 55 and para. 79 of Norris).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Norris within Iliff and Saltzstein. The motivation for doing so would have been to help physicians better manage chronically ill patients (para. 21 of Norris).

(C) Referring to claim 3, Iliff discloses wherein the computer readable medium further comprises instructions executable by the processor to: provide third party access to at least a portion of the first database (para. 92 and para. 292 of Iliff).
(D) Referring to claim 4, Iliff discloses wherein the computer readable medium further comprises instructions executable by the processor to: populate a second database with at least a portion of the data from the first database; and provide third party access to at least a portion of the second database (para. 90 and para. 292 of Iliff).
(E) Referring to claim 5, Iliff discloses wherein the computer readable medium further comprises instructions executable by the processor to: populate a second database with at least a portion of the data from the first database; and transmit the second database to one or more third party systems for access (para. 90 and para. 292 of Iliff).
(F) Referring to claim 8, Iliff does not disclose wherein the computer readable medium further comprises instructions executable by the processor to: validate the first set and the second set of implantable data prior to populating it into the first database.

Saltzstein discloses validating the data sets (col. 7, lines 6-8 & 44-65 of Saltzstein).

Norris discloses receiving data sets from an implantable medical device (para. 79 of Norris).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Saltzstein and Norris within Iliff. The motivation for doing so would have been to detect errors while in

communication with the patient (col. 7, lines 6-8 & 44-65 of Saltzstein) and help physicians better manage chronically ill patients (para. 21 of Norris).
(G) Claims 9-13 repeat substantially the same limitations as claims 1-5 and are therefore rejected for the same reasons given above.

4. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (US 2003/0153819 A1) in view of Saltzstein et al. (5,941,829) in view of Norris et al. (US 2002/0026103 A1), in view of Kelliher et al. (5,857,194), and further in view of Krichen et al. (US 6,250,309 B1).
(A) Referring to claims 6 and 7, Iliff, Saltzstein, Norris, and Kelliher do not disclose wherein the first data set and the second data set from the implantable medical device is in a first format, and wherein the computer readable medium further comprises instructions executable by the processor to: convert the first data set and the second data set implantable medical device from the first format to a second format; and automatically populate the first database with data from the second format and wherein the first format comprises a binary data, and the second format comprises an extensible mark-up language (XML) format.

Krichen discloses wherein the first data set and the second data set from the implantable medical device is in a first format, and wherein the computer readable medium further comprises instructions executable by the processor to: convert the first

data set and the second data set implantable medical device from the first format to a second format; and automatically populate the first database with data from the second format and wherein the first format comprises a binary data, and the second format comprises an extensible mark-up language (XML) format (col. 2, lines 52-61 of Krichen).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Krichen within Illiff, Saltzstein, Norris, and Kelliher. The motivation for doing so would have been to provide a format that can be manipulated at a remote location (col. 2, lines 31-36 of Krichen).

5. Claims 18, 19, 21-24, 28, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (US 2003/0153819 A1) in view of Norris et al. (US 2002/0026103 A1), and further in view of Kelliher et al. (5,857,194).
(A) Referring to claim 18, Iliff discloses a system for automatically populating medical data into a database, comprising:

a microprocessor based controller; a computer readable medium, wherein the computer readable medium includes instructions executable by the microprocessor based controller to (para. 84-85 of Iliff):

receive a first data set that is associated with a first patient, the first data set having a first date and time stamp associated with it (para. 223 of Iliff);

receive a second data set that is associated with the first patient, the second data set having a second date and time stamp associated with it (para. 223 of Iliff);

automatically populate the first data set into a first database having one or more database records associated with the first patient (abstract, para. 90, para. 145, and para. 223 of Iliff); and

automatically populate the second data set into the first database having one or more database records associated with the first patient (abstract, para. 90, para. 145, and para. 223 of Iliff).

Iliff does not expressly disclose: the data sets are from an implantable medical device, and wherein the date and time stamps are configured to act as database record locators.

Norris discloses receiving data sets from an implantable medical device (para. 79 of Norris).

Kelliher discloses wherein the stamps are configured to act as database record locators (col. 3, line 62 – col. 4, line 7 of Kelliher).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Norris and Kelliher within Iliff. The motivation for doing so would have been to help physicians better manage chronically ill patients (para. 21 of Norris), and to find the records by searching (col. 3, line 62 - col. 4, line 7 of Kelliher).

(B) Referring to claim 19, Iliff discloses wherein the computer readable medium further comprises instructions executable by the microprocessor based controller to: receive objective data and subjective data about the first patient (para. 13 of Iliff); and automatically populate the objective data and the subjective data into the first database having one or more database records associated with the first patient (para. 14 of Iliff).

Iliff does not expressly disclose that the data is collected by a physician. However, the feature of a physician collecting patient data is old and well-known, as evidenced by Norris (see para. 7 of Norris).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Norris within Iliff. The motivation for doing so would have been to have someone technically and medically trained to assist the patient (para. 7 of Norris).

(C) Claims 21-24 and 31 repeat the same limitations as claims 2-5 and are therefore rejected for the same reasons given above.

(D) Claims 28 and 29 repeat the same limitations as claims 18 and 19 and are therefore rejected for the same reasons given above.

6. Claims 20 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (US 2003/0153819 A1) in view of Norris et al. (US 2002/0026103 A1), in view of Kelliher et al. (5,857,194), and further in view of Saltzstein et al. (5,941,829).

(A) Referring to claims 20 and 30, Iliff, Norris, and Kelliher do not expressly disclose: validate the objective data and the subjective data prior to automatically populating it into the first database.

Saltzstein discloses validating data (see col. 7, lines 6-8 of Saltzstein).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Saltzstein within Iliff, Norris, and Kelliher. The motivation for doing so would have been to detect errors (col. 7, lines 6-8 of Saltzstein).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff (US 2003/0153819 A1) in view of Norris et al. (US 2002/0026103 A1), in view of Kelliher et al. (5,857,194), and further in view of Krichen et al. (US 6,250,309 B1).
(A) Referring to claim 25, Iliff, Norris, and Kelliher do not disclose wherein the first data set and the second data set from the implantable medical device is in a first format, and wherein the computer readable medium further comprises instructions executable by the microprocessor based controller to: convert the first data set and the second data set implantable medical device from the first format to a second format; and automatically populate the first database with data from the second format.

Krichen discloses wherein the first data set and the second data set from the implantable medical device is in a first format, and wherein the computer readable

medium further comprises instructions executable by the microprocessor based controller to: convert the first data set and the second data set implantable medical device from the first format to a second format; and automatically populate the first database with data from the second format (col. 2, lines 52-61 of Krichen).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Krichen within Illiff, Norris, and Kelliher. The motivation for doing so would have been to provide a format that can be manipulated at a remote location (col. 2, lines 31-36 of Krichen).

Response to Arguments

8. Applicant's arguments filed 7/1/09 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 7/1/09.

(1) Applicant argues that Iliff teaches away from the proposed combination with Saltzstein. Modifying Iliff's system to involve a physician in the collection of data would completely change the principle of operation of Iliff's system, since physician involvement is precisely what Iliff's system is trying to avoid. Modifying Iliff's system as proposed to include an IMD and to obtain information from the IMD also teaches away from the stated goal of Iliff's system.

(A) In response to applicant's arguments that the proposed modification of Iliff is not proper, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, Iliff discloses physician involvement (see paragraphs 76, 136, and 177).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571) 272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./
Examiner, Art Unit 3686
In
10/29/09

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686